ALASKA MEDICAID PHARMACY AND THERAPEUTICS COMMITTEE

Location of Meeting Frontier Building, 3601 C Street, Room 890/896

MINUTES OF MEETING September 25, 2015 8:00 a.m.

Committee Members Present:

Jenny Love, MD, Vice Chair, Acting Marvin Bergeson, MD Robert Carlson, MD (telephonic) Maggie Rader, CNM (telephonic) Charles Semling, Pharm.D. Trish White, R.Ph. (telephonic)

Committee Members Absent:

Robin Cooke, Pharm.D.
Jeffrey Demain, MD, Chair
Vincent Greear, R.Ph.
Diane Liljegren, MD
John Pappenheim, MD
Claudia Phillips, MD
Jill Reid, R.Ph.
John Riley, PA-C

Others Present:

Tolu Balogun, Magellan Medicaid Administration Erin Narus, State of Alaska Jessica Randolph, Kron Associates

1. Call to Order – Chair

Acting Chair Dr. Love called the meeting to order at 8:13 a.m.

2. Roll Call

A quorum was present. Acting Chair Dr. Love reviewed the rules of the meeting.

3. Public Comments - Local Public/Health Practitioners

There were no public comments.

4. Re-Review Acne Agents (Red Category)

There were no public comments.

Ms. Balogun gave the Magellan presentation on Acne Agents. All products included in this review are indicated for the topical treatment of acne vulgaris. It is the most common cutaneous condition in the United States. It is a disorder that affects primarily teenagers and young adults, but it can persist beyond young adulthood. The goal of treatment includes the resolution of lesions, scar prevention, and reduction of psychological morbidities. This is achieved by decreasing the sebaceous gland activity, bacterial population, and inflammation. The available products work by different mechanisms to attack the causative events. In June 2015, there were 251 claims. Since the last review, Onexton was added to the class. Onexton was FDA approved in November 2014. This product is a combination of Benzoyl Peroxide and Clindamycin Phosphate in the form of a topical gel. It is indicated for the once daily treatment of inflammatory and non-inflammatory acne in patients 12 and older. It is classified as Pregnancy Category C. As with Clindamycin continuing products, it is contraindicated in patients with a history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis. At the last review, a motion for therapeutic alternatives, to include one drug from each subclass, passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE ONE DRUG FROM EACH SUBCLASS. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

5. Re-Review OF Alzheimer's Agents (Red Category)

There were no public testimonies.

Ms. Balogun gave the Magellan presentation on Alzheimer's Agents. Alzheimer's disease is an irreversible decline in memory and cognition outside the baseline of normal agent. This condition is characterized by progressive cognitive decline associated with impairment of activities of daily living and behavioral disturbances. Patients with Alzheimer's disease eventually lose all cognitive, analytical, and physical functioning. Acetylcholinesterase Inhibitors exert their therapeutic effect by enhancing cholinergic function. Each of these drugs has shown cognitive benefit over placebo. However, it remains unclear if they slow progression, cognitive decline, delays placement in nursing homes, or alters mortality. Memantine, an NMDA receptor antagonist, has been shown to improve cognition in moderate to severe dementia. Serious skin reactions have been reported with the use of Galantamine and Galantamine ER. All Cholinesterase Inhibitors must be slowly titrated upwards to minimize GI adverse effects. In June 2015, there were 112 claims. Significant changes include the addition of Namzaric to the class. Namzaric was FDA approved in December 2014. It is indicated for the treatment of moderate to severe dementia in Alzheimer's disease. It is a fixed dose combination of Donepezil and Memantine ER. It is classified as Pregnancy Category C. At the last review, a motion for therapeutic alternatives, to include one from each mechanism of action, passed unanimously.

DR. RADER MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTNERATIVE. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

6. Re-Review of Restless Leg Syndrome (Red Category)

There were no public testimonies.

Ms. Balogun gave the Magellan presentation on Restless Leg Syndrome (RLS). RLS is a neurological sensory disorder in which patients experience irrepressible sensations in the arms or legs while sitting or laying still to cause them to move their arms or legs. Providers will need to rule out other movement disorders with similar symptoms to RLS. Pharmacologic treatments have been used to alleviate symptoms, severity, and improve quality of life. Historically, RLS has been treated with opioids, benzodiazepines, anticonvulsants, and dopaminergic agents. Newer studies suggest that RLS is associated with the dopamine system and depletion of iron stores. The 2012 American Academy of Sleep Medicine RLS practice parameters commend Pramipexole (Mirapex) and Ropinirole (Requip) for RLS. Horizant, which is the only form of Gabapentin used to treat RLS, is also recommended. In June 2015, there were 147 claims. Significant changes since the last review include Rytary being added to the Anti-Parkinson's agent class. Rytary was approved by the FDA in January 2015. It is indicated for the treatment of Parkinson's disease. The agent is an extended release oral capsule formulation of Carbidopa and Levodopa. It is classified as Pregnancy Category C. At the last review, a motion for class effect passed unanimously.

DR. SEMLING MOVED A CLASS EFFECT. SECONDED BY DR. BERGUSON. THE MOTION PASSED UNANIMOUSLY.

7. Re-Review of Phosphate Binders (Red Class)

There were no public testimonies.

Ms. Balogun gave the Magellan presentation on Phosphate Binders. The agents in this class are used in chronic kidney disease or end stage renal disease to reduce serum phosphorus and prevent hyperphosphatemia. As kidney function deteriorates, the levels of phosphorus increase, which results in hyperphosphatemia. Elevated levels inhibit the conversion of 24-hydroxyvitamin D to calcitriol. The reduction in calcitriol decreases intestinal absorption of calcium and eventually leads to hypocalcaemia. Hyperphosphatemia can lead to severe complications such as renal bone disease and estraosseous calcification, including cardiac calcification and increase the risk of death. In June 2015, there were 61 claims. Significant changes include Auryxia being added to the class. Auryxia was approved by the FDA in September 2014. It is indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis. Auryxia contains ferric iron, which binds dietary phosphate in the GI tract and precipitates as ferric phosphate, which is excreted in the stool, thereby decreasing the body's phosphate absorption and serum concentrations. It is contraindicated in patients with iron overload syndromes. Iron parameters should be assessed prior to initiating therapy and thereafter. It is classified as Pregnancy Category B. The safety and efficacy of Auryxia has not been established in pediatric patients. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

8. Re-Review of Multiple Sclerosis (Red Class)

CONTESSA FINCHER, a representative of Teva Neurosciences, discussed Glatiramer (Copaxone). Copaxone is (indiscernible -- unable to hear caller). The difference between the 20-milligram once

daily formulation and the 40-milligram three times weekly formulation was discussed. In terms of efficacy, both products are similar. (Indiscernible -- unable to hear caller.) In terms of tolerability, a new public study shows that when patients switch from 20 milligrams to 40 milligrams, they experience a 50 percent reduction in site reactions. Therefore, Copaxone 40 milligrams need a better patient tolerability profile than the 20-milligram formulation. In terms of safety, they are both Pregnancy Category B and there are no additional requirements for monitoring or testing of liver enzymes or blood chemistry. There are no warnings about depression or serious infection. We request that patients have access to the 40-milligram dosage, as a preferred agent, on the Alaska PDL.

MARY KEMHUS, a representative of Novartis, discussed Fingolimod (Gilenya). Multiple published clinical trials have shown that Gilenya has shown efficacy across all four MS measures including disability, relapse rates, MRI activity, and brain volume loss. It is the only oral drug that has head-to-head superiority data comparing it to other disease modifying therapies to treat MS. Several trials and their outcomes were reviewed. Patients who switched to Gilenya from Avonex had a 29 percent improvement in their annualized relapse rate, but never caught up to the benefit that was seen in those patients who initially started with Gilenya. In clinical trials, Gilenya has demonstrated low discontinuation rates due to adverse events. It has been on the market for five years and has extensive real-world experience with more than 120,000 patients treated and 220,000 patient years of exposure. Please refer to the PI for a label change in August on updated warnings and precautions. In summary, Gilenya is the only oral disease-modifying therapy, it has shown superior efficacy to injectable therapy, it shows consistent and sustained efficacy across all four MS measures, and it seems to be a well-tolerated option for patients with relapsing forms of MS. For these reasons, we request that Gilenya be placed in a preferred position on the Alaska Medicaid PDL.

Ms. Balogun gave the Magellan presentation on Multiple Sclerosis Agents (MS). MS is an autoimmune inflammatory disease of the central nervous system (CNS). The etiology is unknown and it is characterized as demyelination and axonal degeneration. The nerve degeneration associated with MS an result in a wide variety of symptoms including sensory disturbances in the limbs; optic nerve dysfunction; ataxia; fatigue; and bladder, bowel, and sexual dysfunction. Severe cases may result in partial or complete paralysis. Cognitive impairment is also seen in about 50 percent of patients. All of the oral and injectable agents are indicated for the relapsing form of MS to reduce frequency of exacerbations, except for the oral agent Dalfampridine, which is indicated to improve walking in patients with MS. In June 2015, there were 20 claims. Significant changes include Plegridy being added to the class. Plegridy was approved by the FDA in August 2014. It is a pegylated formulation indicated for the treatment of patients with relapsing forms of MS. It is available as a single dose, prefilled pen for subcutaneous administration. It is classified as Pregnancy Category C. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. SEMLING MOVED THE DRUGS IN THE CLASS ARE THERAPEUTIC ALTERNATIVES TO INCLUDE ONE INJECTIBLE AND ONE ORAL FORMATION AS PREFERRED AGENTS. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

9. Re-review of Antiemetic/Antivertigo Agents (Red Class)

PARVONEH NAVAS, a representative of Eisai, discussed Netupitant/Palonosetron (Akynzeo). Akynzeo is the first combination antiemetic approved by the FDA. It is an oral fixed combination of two antiemetic agents, Netupitant and Palonosetron, both of which are anti-nausea and antiemetic agents. Akynzeo is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including but not limited to highly emetogenic chemotherapy. Chemotherapy-Induced Nausea and Vomiting (CINV) remains one of the most distressing symptoms associated with cancer therapy, and patients consider CINV as one of the most troubling side effects of such treatment. Prevention of CINV is an important component of supportive care for patients receiving chemotherapy. The efficacy and safety of Akynzeo was established in three multi-center, randomized, double-blind pivotal trials, which were reviewed. Based on the information provided, we seek unrestricted access to Akynzeo in patients receiving cancer chemotherapy.

Ms. Balogun gave the Magellan presentation on Antiemetic/Antivertigo Agents. Chemotherapyinduced vomiting (emesis) and nausea can significantly impact a patient's quality of life, leading to poor compliance with future chemotherapy or radiation treatments. The goal of antiemetic therapy is to prevent nausea and vomiting complete. Nausea and vomiting of pregnancy can occur at any time of the day and effect pregnant women with varying symptoms. There are several agents in this class. The NK₁ receptor antagonist exerts its main antiemetic action by occupying the brain P/NK₁ receptors. This receptor pathway regulates the behavioral responses to a range of noxious and stressful stimuli. The 5-HT₃ antagonist selectively blocks 5-HT₃ receptors. The mechanism of action of these drugs has not been fully elucidated. The Cannabinoids act on the cannabinoid receptor (CB1 and CB2) in the brain. These receptors are believed to regulate nausea and vomiting. The antihistamines act on the vomiting center and vestibular pathways. The mechanism of action of Diclegis, which is a fixed dose combination of antihistamines, is unknown for the treatment of nausea and vomiting of pregnancy. The phenothiazines block postsynaptic dopaminergic receptors in the brain, including the chemoreceptor trigger zone. The antidopaminergic agents include Metoclopramide, which aides in gastric motility increasing emptying and intestinal transit. It blocks the dopaminergic activity to the medullary chemoreceptor trigger zone. Diclegis is classified as Pregnancy Category A and is intended for use in pregnant women, but all of the other agents in this class are either Pregnancy Category B or C. In June 2015, there were 681 claims. Significant changes include the addition of Akynzeo to the class. At the last review, a motion for therapeutic alternatives, to include at least one Pregnancy Category A agent, passed unanimously.

In response to Dr. Semling, Ms. Narus said the classifications, which were developed by Magellan based on the rebate structure, do not include other agents that could be used for nausea and vomiting.

DR. SEMLING MOVED THE AGENTS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

10. Re-review of Antipsoriatics - Topical (Red Class)

There were no public testimonies.

Ms. Balogun gave the Magellan presentation on Antipsoriatics - Topical. Psoriasis is a chronic, autoimmune disease that appears on the skin. It is estimated that psoriasis affects approximately 7.5 million people in the United States. There are five types of psoriasis: plaque, guttate, inverse, pustular,

and erythrodermic. The most common type is plaque psoriasis in which patches or lesions of skin become inflamed and is covered by a silvery white scale. The plaques frequently occur on the skin of the elbows and knees but can affect any area including the scalp. The 2011 Evidence-Based Clinical Practice Guidelines, developed by the American Academy of Dermatology, indicates that approximately 80 percent of patients affected with psoriasis have mild to moderate disease that can be managed with topical agents. In June 2015, there were 11 claims. Significant changes include the following. Taclonex is now indicated for the treatment of psoriasis of the skull in patients 12 years and older. Pediatric recommended dosage is to apply the ointment once daily for up to four weeks or eight weeks for the suspension. Weekly dosage recommendations are not to exceed 60 grams. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. WHITE. THE MOTION PASSED UNANIMOUSLY.

11. Re-Review of Pancreatic Enzymes (Green Class)

Dr. Balogun gave the Magellan presentation on Pancreatic Enzymes. The pancreas secrets enzymes necessary for digestion and neutralizes gastric acid to achieve the appropriate pH needed to maintain activities of enzymes. The agents in this class supplement pancreatic enzymes when indigenous function is lost. This loss of indigenous function occurs in conditions of cystic fibrosis, chronic pancreatitis, pancreatic tumors, and absence of all or part of the pancreas. Pancreatic enzymes supplements differ primarily in enzyme content and bioavailability. In general, these products have demonstrated favorable risk-benefit profiles in the treatment of exocrine pancreatic insufficiency. In June 2015, there were 63 claims. At the last review, a motion for class effect, to include at least one pediatric preparation, passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE AT LEAST ONE PEDIATRIC PREPARATION. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

12. Re-Review Skeletal Muscle Relaxants (Green Class)

Ms. Balogun gave the Magellan presentation on Skeletal Muscle Relaxants. Skeletal muscle relaxants are FDA approved to treat two different types of conditions: muscular pain or spasms and spasticity. Both conditions affect patients' mobility and affect independence in activities of daily living and work. The agents in this class consist of antispasticity and antispasmodic agents. The antispasticity agents, such as Baclofen and Tizanidine, aid in reducing muscle hypertonicity and involuntary jerks. Antispasmodic agents, such as Carisoprodol and Cyclobenzaprine, are primarily used to treat musculoskeletal conditions. In June 2015, there were 1,604 claims. At the last review, a motion for class effect passed with one abstention.

In response to Acting Chair Dr. Love, Ms. Balogun said the "retired" watermark in the background of the provided materials indicate there have not been any significant changes for a while.

DR. SEMLIN MOVED A CLASS EFFECT. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

13. Re-Review of Bone Resorption Suppression and Related Agents (Green Class)

Ms. Balogun gave the Magellan presentation on Bone Resorption Suppression and Related Agents. Osteoporosis is characterized by the deterioration of bone tissue and low bone mass. There are three categories of osteoporosis: postmenopausal, age-related, and secondary osteoporosis. The primary goal of treatment is to reduce fracture risk. This can be done by reducing bone loss, increasing bone mass, improving bone architecture to maintain bone strength, and minimizing or eliminating factors that may contribute to fractures. In June 2015, there were 159 claims. At the last review, a motion for therapeutic alternatives, to include at least one non-daily use bisphosphonate, passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES, TO INCLUDE AT LEAST ONE NON-DAILY BISPHOSPHONATE. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

14. Re-Review of Erythropoiesis Stimulating Proteins (Green Class)

Ms. Balogun gave the Magellan presentation on Erythropoiesis Stimulating Proteins. Erythropoietin is a glycoprotein produced in the kidneys that stimulates red blood cell production from bone marrow. It acts on the erythroid progenitor cells in the bone marrow to cause late differentiation and maturity of the red blood cells. The 2004 National Comprehensive Cancer Network guidelines states that erythropoiesis stimulating agents are associated with an increased risk of thrombosis, decreased survival, and shortened time to tumor progression. Physicians are advised to use the lowest dose possible to maintain hemoglobin levels sufficient to avoid blood transfusions, to prescribe according to FDA guidelines using the REMS program, and to obtain patient consent. These agents should be discontinued once the cause of chemotherapy has been completed and anemia resolves. In June 2015, there were 11 claims. At the last review, a motion for therapeutic alternatives passed unanimously.

DR. WHITE MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

15. Re-Review of Topical Steroids - Low Potency (Green Class)

Ms. Balogun gave the Magellan presentation on Topical Steroids - Low Potency. The exact mechanism of action of the topical corticosteroids is not completely understood. These agents are felt to induce phospholipase A2 inhibitory proteins, or lipocortins, which control the biosynthesis of mediators of inflammation, such as prostaglandins and leukotrienes, by inhibiting the release of arachidonic acid. Corticosteroids are classified by potency. These low-potency agents have varying indications including relief of inflammation, treatment of mild to moderate atopic dermatitis, and treatment of seborrheic dermatitis of the scalp. In June 2015, there were 222 claims. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

16. Re-Review of Topical Steroids - High Potency (Green Class)

Ms. Balogun gave the Magellan presentation of Topical Steroids - High Potency. Topical corticosteroids are used for a variety of inflammatory skin conditions. The agents in this class are indicated for the relief of inflammatory and pruritic manifestations of corticosteroid-responsive dermatitis. Topicort spray is only approved for the treatment of plaque psoriasis in patients 18 years of age and older. In June 2015, there were 512 claims. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

17. Re-Review of Antihyperuricemics (Green Class)

Ms. Balogun gave the Magellan presentation on Antihyperuricemics. Hyperuricemia can occur due to either an overproduction of uric acid, an under excretion of uric acid, or a combination of the two mechanisms. Gout is the crystal deposition of monosodium urate associated with elevated levels of uric acid. Crystals are deposited in joints, tendons, and surrounding tissues. Treatment is managed in three stages: acute treatment, prophylaxis to prevent acute flares, and lowering excess stores of urate. Acute gouty arthritis can be treated with colchicine, nonsteroidal anti-inflammatory drugs (NSAIDs), and intra-articular corticosteroid injections. In June 2015, there were 215 claims. At the last review, a motion for therapeutic alternatives, to include at least one Xantine Oxidase inhibitor, one Colchicine product, and one Uricosuric product, passed unanimously.

DR. RADER MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

18. Re-Review of Antimigraine Agents (Green Class)

Ms. Balogun gave the Magellan presentation on Antimigraine Agents. Criteria for the diagnosis of migraine headaches includes an episodic headache lasting from four to 72 hours with at least two of the following symptoms: unilateral pain, throbbing, aggravation of pain upon moving, pain of moderate to severe intensity accompanied by nausea, vomiting, photophobia, or phonophobia. Treatment of acute migraine attacks includes acetaminophen, NSAIDs, and the ergot alkaloids. NSAIDs, or combinations such as aspirin plus acetaminophen plus caffeine, are recommended as first-line therapy for those patients with mild to moderate migraine pain. Migraine-specific agents like triptans should be used in patients whose migraine attacks do not respond to NSAIDs. In June 2015, there were 233 claims. At the last review, a motion for class effect, to include at least one oral and one subcutaneous formulation, passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT, TO INCLUDE ONE ORAL AND SUBCUTANEOUS FORMUATION. SECONDED BY DR. WHITE. THE MOTION PASSED UNANIMOUSLY.

19. Re-Review of BPH Treatments (Green Class)

Ms. Balogun gave the Magellan presentation on BPH Treatments. BPH is one of the most common conditions in aging men. The symptoms are induced by hyperplasic changes in prostate tissue, leading to prostatic enlargement. The resulting obstruction increases urinary outflow resistance and results in an impaired detrusor muscle response. The 2010 American Urological Association (AUA) guidelines state that alpha-blockers are appropriate treatment options for patients with lower urinary tract symptoms secondary to BPH. Although there are slight differences in the adverse event profiles of these agents, the AUA states that these agents have equal clinical effectiveness. In June 2015, there were 420 claims. At the last review, a motion for therapeutic alternatives, to include at least one alphablocker and one androgen hormone inhibitor, passed unanimously.

DR. BERGESON MOVED THE DRUGS IN THE CLASS WERE THERAPEUTIC ALTERNATIVES TO INCLUDE AT LEAST ONE ALPHA-BLOCKER AND ONE ADROGEN HORMONE INHIBITOR. SECONDED BY DR. WHITE. THE MOTION PASSED UNANIMOUSLY.

20. Re-Review of Pulmonary Arterial Hypertension Agents (Green Class)

Ms. Balogun gave the Magellan presentation on Pulmonary Arterial Hypertension Agents. The treatment for pulmonary arterial hypertension is challenging and complicated. Untreated, the condition is characterized by a progressive increase in pulmonary arterial pressure, secondary right ventricular failure, and premature death. Symptoms include dyspnea, dizziness, syncope, fatigue, edema, angina, palpitations, and other symptoms, all of which are exacerbated by exertion. In June 2015, there were 11 claims. At the last review, a motion for therapeutic alternatives, to include one PDE5 Inhibitor, one oral non-PDE5 inhibitor, and one inhaled product, passed unanimously.

Ms. Narus noted that new information on this class was published after the agenda was set. The committee has the option of deferring or tabling this class to the November meeting so the additional information can be considered.

AFTER DISCUSSION AND WITHOUT OBJECTION, THE COMMITTEE AGREED TO TABLE THE PULMONARY ARTERIAL HYPERTENSION AGENTS REVIEW UNTIL THE NOVEMBER MEETING.

21. Re-Review of Topical Steroids - Medium Potency (Green Class)

Ms. Balogun gave the Magellan presentation on Topical Steroids - Medium Potency. Agents in this class are indicated for the relief of inflammatory and paretic manifestations of corticosteroid responsive dermatoses. They are classified as having medium potency relative to the other corticosteroids. In June 2015, there were 100 claims. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECONDED BY DR. RADER. THE MOTION PASSED UNANIMOUSLY.

22. Re-Review of Topical Steroids - Very High Potency (Green Class)

Ms. Balogun gave the Magellan presentation on Topical Steroids - Very High Potency. The agents in this class are indicated for the relief of inflammatory and paretic manifestations of corticosteroid responsive dermatoses. They are classified as having very high potency relative to the other corticosteroids. In June 2015, there were 84 claims. At the last review, a motion for class effect passed unanimously.

DR. BERGESON MOVED A CLASS EFFECT. SECNDED BY DR. SEMLING. THE MOTION PASSED UNANIMOUSLY.

23. Re-Review of Progestins for Cachexia (Green Class)

Ms. Balogun gave the Magellan presentation on Progestins for Cachexia. Cachexia is a complex syndrome that includes weight loss, lipolysis, loss of muscle and visceral protein, anorexia, chronic nausea and weakness. Both formulations of Megestrol Acetate suspension are clinically effective in increasing food intake, resulting in weight gain. There are two agents in this class, Megace and Megace ES. Megestrol Acetate is a synthetic derivative of Progesterone. The exact mechanism of action as an appetite-enhancing agent in Cachexia is unknown. Both agents are classified as Pregnancy Category X. Caution should be used in the geriatric population due to a greater potential for decreased hepatic, renal, and cardiac function. In June 2015, there were 12 claims. At the last review, a motion for class effect passed unanimously.

DR. SEMLING MOVED A CLASS EFFECT. SECONDED BY DR. BERGESON. THE MOTION PASSED UNANIMOUSLY.

24. Break as Needed

Break from 9:14 a.m. to 9:22 a.m.

25. Review Minutes from April 2015 Meeting

Acting Chair Dr. Love said the April 2015 meeting minutes were not provided in the committee materials and would be reviewed at the November meeting.

26. Comments from Committee Members or Chair

Acting Chair Dr. Love noted the next meeting was Friday, November 20, 2015.

27. Adjourn

WITHOUT OBJECTION, THE MEETING WAS ADJOURNED.

The meeting adjourned at 9:23 a.m.